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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,302	02/08/2001	Rango Dietrich	P66333USO	4778

136 7590 08/23/2004

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,302	DIETRICH ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (2 months-granted), the Amendment and Applicant's Arguments/Remarks, all filed 02/24/04 is acknowledged.

Claims 21-43 are pending. New claims 35-43 have been added. Claims 1-20 have been previously cancelled. Claims 21-43 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US Pat. No. 5,260,069) in view of Dietrich *et al.* (WO 97/02020).

Chen teaches a unit dosage form for delivery drugs into the body, wherein a plurality of populations of pellets is provided within a unit dosage form such as a capsule (Abstract). The plurality of pellets or particles are completely enclosed within said capsule, each population of pellets constructed to release a drug into said environment of use, whereby all of said pellets are released from said capsule substantially simultaneously, and exposed to the environment when the capsule disintegrates (col. 6, claim 1). Each pellet contains a core including a drug and a swelling agent, which can be crospovidone (col. 6, claim 1 and col. 7, claim 6). Additionally, each pellet is coated with a coating membrane containing (a) a water insoluble, permeable polymer and one or both of (b) a diffusion controlling agent, and (c) a dissolution controlling agent (col. 3, lines 10-16). The water insoluble film former can be a cellulose derivative, an acrylic resin, a copolymer of acrylic acid and methacrylic acid esters with quaternary ammonium groups, or copolymers of acrylic acid and methacrylic acid esters (col. 7, claim 7). The water-soluble film former can be a phthalate, HPMC, shellac and others (col. 7, claim 9). Chen does not teach the use of a specific drug in his formulation, instead he teaches that the formulation can be used with a variety of active agents (col. 3, lines 31-32).

Dietrich *et al.* teach an oral pharmaceutical composition of pantoprazole in pellet or tablet form, wherein the drug is at least partly in slow release form, and is administered in combination with an antimicrobial active (Abstract). Furthermore, Dietrich *et al.* teach that the slow release has a core, at least one intermediate layer controlled release of the active agent and

an outer enteric layer, which is soluble in the small intestine. Additionally, Dietrich *et al.* teach that the intermediate coating can be a methacrylate polymer (Eudragit). Dietrich *et al.* also teach that traditional excipient can be included, such as cross-linked polyvinylpyrrolidone as a disintegrant (p. 8, last line).

It is the position of the Examiner that one of ordinary skill in the art would have been motivated to combine the teachings of Chen and Dietrich *et al.*. Chen discloses a new type of dosage form, comprising a capsule containing pellets with varying rates of release. Chen does not specify any particular active agent or class of active agents to be used with his invention.

Dietrich *et al.* is relied upon for the teaching that benzimadazoles, including pantoprazole, are known in formulations with varying release. Furthermore, Dietrich *et al.* is relied upon to show that varying rates of release is beneficial for an active agent, such as benzimadazole, which is desired to have effects over a long period of time. One skilled in the art would have been motivated to use an active, such as disclosed by Dietrich *et al.*, in a new type of formulation, such as that disclosed by Chen. The expected result would be a successful pharmaceutical formulation, with varying release rates, so that the active agent may have the desired effect over a longer period of time. Taking a known type of dosage form, such as the system disclosed by Chen, and using a known active agent in the formulation, is not patentable, absent a showing of criticality or unexpected results. For these reasons, this invention as a whole would have been *prima facie* obvious to one or ordinary skill in the art at the time the invention was made.

This rejection is maintained and applied to newly added claims 35-43.

The prior art teaches oral unit dosage forms comprising a combination of active ingredients, tablet disintegrants and film forming polymers, for example, in varying rates of release.

Response to Arguments

Applicant's arguments filed 02/24/04 have been fully considered but they are not persuasive.

Applicant argued, "Dietrich et al. relates to a gastric acid protected (i.e., enteric coated) oral dosage form. The slow release from of pantoprazole (which is covered behind an enteric coating) will have a complete different release profile as compared to the administration form of the invention, wherein the sustained release coating is not covered by an additional enteric coating. Chen relates to a new dosage form, comprising a capsule containing pellets with varying rates of release. Chen does not address the problem of benzimidazoles, which are part of the present invention, which are sensitive to gastric acid. Neither Chen nor Dietrich suggest providing benzimidazoles without enteric coating, but with a sustained release coating. The Dietrich reference actually teaches away from using the Chen reference."

These arguments have been fully considered, but were not found to be persuasive.

Chen, as discussed above, teaches a unit dosage form for delivery drugs into the body, wherein a plurality of populations of pellets is provided within a unit dosage form such as a capsule. Chen teaches that a combination of different therapeutic agents can be used, that

include, for example, antibiotics (see col. 5, lines 17-22). Chen does not explicitly teach the use of benzimidazoles in his formulation. Dietrich *et al.* is relied upon for the teaching of benzimidazoles, including pantoprazole, that is used in combination with antimicrobially-active agents (see pg. 4, lines 6-11 and abstract). Ample motivation is provided by the prior art since Chen teaches a unit dosage form that provides for various rates of release and includes drugs, such as antibiotics, and similarly, Dietrich *et al.* teach that antimicrobial agents used in combination with benzimidazoles, particularly pantoprazole, enhances and distinguishes the action of the antimicrobial agent as compared to the antimicrobial agent being provided alone. The combination taught by the prior art renders the instant invention obvious. The prior art teaches a similar product formulation comprising similar ingredients for the same intended purpose and to solve the same problem as the Applicant. Hence, the instant invention is rendered prima facie obvious over the cited prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

August 17, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600